

## IN THE USE ED STATES PATENT AND TRADEMARK OFFICE



Serial No.:

10/804,576

Confirmation No.:

7069

Applicants:

Frederick H. Miller

Filed:

March 19, 2004

Art unit:

1615

Examiner:

Aradhana Sasan

For:

MULTI-PHASE, MULTI-COMPARTMENT CAPSULAR DELIVERY APPARATUS AND

METHODS FOR USING SAME

Attorney Docket No.: 159.1001

MAIL STOP: AMENDMENT Commissioner for Patents Alexandria, VA 22313-1450 April 13, 2009

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R.§ 1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record documents listed on the accompanying Form PTO-1449 (1 page) for consideration by the Examiner in connection with the examination of the above-identified patent application.

During the Interview conducted on April 9, 2009 between the undersigned and Examiners Woodward and Sasan, the undersigned discussed certain prior art of record and also discussed additional information which, while not necessarily prior art, was information that might prove helpful to the Examiner's understanding of the claimed invention and other documents submitted during prosecution of the present application.

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First, the undersigned briefly discussed the materials submitted in the Information Disclosure Statement dated February 12, 2009 pertaining to a litigation between the assignee of the present application, Innercap Technologies, Inc. and Nutrex Research, Inc. Therein, there were comments made concerning technology allegedly developed by Capsugel and Pfizer concerning liquid encapsulation. The undersigned showed the Examiners publically available information found by the undersigned (in preparation for the interview) on the internet concerning the Capsugel Liquid Formulation technology. This information is now made of record herein in the present Information Disclosure Statement. The undersigned did not undertake an extensive search concerning the Capsugel/Pfizer technology, but is not aware of anything further concerning the Capsugel/Pfizer technology. Further, the undersigned is not taking a position as to whether the Capsugel information submitted herewith is in of itself prior art or not.

Next, the undersigned briefly discussed US Patent Nos. 6,528,809 and 6,702,683 assigned to Microdose Technologies, Inc. These patents were brought to inventor Fred Miller's attention by Microdose. It is not believed that these patents are particularly relevant, but are cited on the accompanying PTO-1449 form for completeness of the record. The undersigned during the interview discussed the fact that WO 02/096347 (also assigned to Microdose Technologies, Inc) was previously made of record in the Information Disclosure Statement of February 12, 2009. The Examiner is requested to review these references and make her own determination concerning the relevance of these references.

An additional set of information is made of record at this time concerning Industry publications concerning the Innercap technology which is the subject of the present application. This information is as follows: A brochure by ONdrugDelivery Ltd dated 2007 (the Introduction by Publisher Guy Furness briefly discusses the Innercap technology in the third column, first paragraph, and an article prepared by ONdrugDelivery on behalf of InnerCap Technologies begins on page 12; an Article from Drug Delivery Technology Magazine from October 2005 (Vol. 5, No. 9) includes an article by Contributor Cindy H. Dubin entitled "Combination Products: Strategies for a Continuous Pipeline" and includes commentary by Jay S. Trivedi, former Director, New

Products Department at Schwarz Pharma USA concerning multi-compartment capsules, and commentary concerning the same by inventor Fred Miller; Drug Delivery Report Autumn/Winter 2005 contains an article entitled "Combination Products: Industry Strategies and Innovation Takes Combination Products to New Levels" with advertisements for the technology covered by the presently claimed invention; market news presented in Drug Delivery Technology Magazine for July/August 2004 (Vol. 4 No. 6) entitled "InnerCap Technologies Develops New Capsule Drug Delivery System"; an article from InPharma.com from May 27, 2004 entitled "Combo Pills Made Simple with Capsule Tech"; and an article from Pharmaceutical Technology July 2004 entitled "Multicompartment Capsules Prove Less is More" by Doreen R. Coppola cited on the accompanying PTO-1449 form. Also enclosed is a Brochure from assignee InnerCap Technologies, Inc.

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Finally, a set of information is provided concerning commercialized products: an advertisement by Health International Products, Inc.; an advertisement concerning energyXcentric <sup>TM</sup>; an advertisement concerning dietXcentric <sup>TM</sup>; and an advertisement in Muscle Fitness® Magazine concerning Nutrex® product Lipo® 6X. The undersigned is advised that the dietXcentric and the energyXcentric is under license from InnerCap and being sold through retail stores. The Examiner's attention is respectfully directed to the Information Disclosure Statement filed February 12, 2009 with respect to the Nutrex v. InnerCap litigation. For example, in reference A06, Nutrex alleges that Nutrex has sold the Lipo-6® supplement since May of 2002, and further states that a license between the companies was entered into on June 1, 2006, and alleges various breaches of the License Agreement by InnerCap. Finally, enclosed is an 8 page advertisement from Capsugel entitled "The Hard Gelatin Capsule Advantage".

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c), "before the mailing date of any final action under § 1.114," and is accompanied by check in to the amount of \$180.00 for the fee set forth in § 1.17(p). If it is determined that any additional fee is due or an overpayment has been made in connection with the filing of this Information Disclosure Statement, the Examiner is authorized to charge said fee or to credit said overpayment to Attorney Deposit Account No. 50-0552.

Respectfully submitted,

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